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UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF WASHINGTON
AT SEATTLE

UNITED STATES OF AMERICA *ex rel.* [FILED UNDER SEAL],

Plaintiffs-Relators,

v.

[FILED UNDER SEAL],

Defendants.

FILED UNDER SEAL

DO NOT PLACE ON PACER

CIVIL ACTION NO.: 2:21-CV-00582 RSM

FALSE CLAIMS ACT COMPLAINT AND DEMAND FOR JURY TRIAL

[FILED IN CAMERA AND UNDER SEAL]

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RELATOR'S COMPLAINT UNDER THE FALSE CLAIMS ACT

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Plaintiff-Relator Expose Healthcare Fraud, LLP ("Relator"), on behalf of the United States of America, brings this action against Defendants Biofrontera AG and Biofrontera Inc. (collectively "Biofrontera") for violations of the False Claims Act, 31 U.S.C. § 3729, et seq., to recover all available damages, civil penalties, and all other recoveries.

I. SUMMARY OF THE CASE

1. Tens of millions of Americans suffer from actinic keratoses, dangerous skin lesions that if not successfully treated, can lead to fatal skin cancer. Actinic keratoses disproportionately affect older Americans, and as a result, most patients suffering from actinic keratoses receive healthcare coverage through Medicare.

2. Biofrontera is a German company that manufactures Ameluz, an expensive prescription product used in the treatment of actinic keratoses. In 2016, Biofrontera launched Ameluz in the United States into a very competitive and concentrated marketplace, largely pegging the financial viability of the company upon rapid success in the United States. Biofrontera sought to quickly capture market share by deploying a variety of aggressive tactics, which included the perpetration of systematic, multifaceted, and nationwide kickback and off-label marketing schemes.

3. To encourage use of Ameluz, Biofrontera provides physicians with free Ameluz with paid orders of Ameluz. In other words, Biofrontera pairs paid units with free units, which are internally referred to as "training tubes" at the company. Though described as training tubes, Biofrontera gives free Ameluz to repeat customers with long-established relationships. The real reason for giving away these expensive products is to incentivize physicians to purchase, and to continue purchasing, Ameluz.

4. Medicare reimburses for Ameluz on a "buy and bill" basis, meaning that providers are required to pay for the product up front and then bill Medicare after using the product with a Medicare beneficiary. Typically, providers receive a reimbursement amount that is only modestly more than the acquisition cost. Exploiting this reimbursement model, Biofrontera utilizes these "training tubes" of Ameluz as a currency to provide physicians with a lucrative kickback: the ability to receive reimbursement for an expensive product for which they

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did not pay, while simultaneously defraying physicians' out-of-pocket costs. Instead of receiving only a modest mark-up from their acquisition costs as they typically would, physicians are able to profit from the entire reimbursement amount, which is particularly significant given that Ameluz is an expensive product. In this way, Biofrontera's provision of free Ameluz is functionally equivalent to providing cash to physicians.

5. Compounding its misconduct, Biofrontera also engaged in pervasive off-label marketing of Ameluz by promoting uses of Ameluz that violated the FDA-approved instructions for use. Ameluz is only FDA-approved for use with a red-light lamp, a product that only Biofrontera distributes in the United States and that costs about $7,500. When Ameluz launched in the United States in 2016, most physicians only had blue-light lamps (because the primary competitor to Ameluz was approved for use with blue-light lamps) and were not inclined to spend thousands of dollars to acquire a new lamp. Thus, Biofrontera told physicians to simply use Ameluz with their existing blue-light lamps, even though Ameluz is only FDA-approved for red-light lamps. Likewise, Biofrontera told physicians they could utilize a shorter incubation period than the FDA-approved incubation period. Both of these are flagrant examples of off-label marketing that, in addition to being illegal, had important health and safety ramifications for patients.

6. Relator is an LLC whose sole member previously worked as a sales manager at Biofrontera and witnessed Biofrontera's misconduct firsthand, including how Biofrontera implemented this misconduct nationwide by first training new sales representatives how to effectuate the kickback and off-label marketing schemes, and subsequently by issuing verbal instructions—which were never memorialized in writing—from its central office to sales representative who were "on the ground."

7. Reimbursement claims to government payors (including Medicare) that are tainted by Biofrontera's kickbacks violate the Anti-Kickback Statute and the False Claims Act ("FCA"). Biofrontera's off-label marketing of Ameluz provides an independent basis for FCA liability. Biofrontera is liable under the FCA for causing the presentment of false claims tainted by the kickbacks and off-label marketing.

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II. THE PARTIES

A. The Government

8. The United States is a plaintiff to this action on behalf of the Department of Health and Human Services ("HHS"), the Centers for Medicare and Medicaid Services ("CMS"), and federally funded healthcare programs, including Medicare, Medicaid, and the Veterans Health Administration.

9. Medicare is a health insurance program funded by the federal government that provides health insurance benefits to (1) individuals who are 65 or older, (2) individuals with certain disabilities, and (3) individuals suffering from end-stage renal disease. *See* 42 U.S.C. § 1395c.

B. Relator

10. Relator is a limited liability company organized in Delaware.

11. A partner of Relator is a former Biofrontera employee ("Whistleblower") that has worked in medical sales for approximately 15 years.

12. Whistleblower worked at Biofrontera from January 2018 until June 2020 as the territory manager for Virginia, Maryland, and Washington D.C. In this role, Whistleblower was the sole sales representative for these areas.

13. Through his role, Whistleblower had direct insight into Biofrontera's sales and marketing practices, including the illegal kickbacks at issue in this lawsuit.

14. Relator and Whistleblower are collectively referred to herein as "Relator" unless otherwise specified.

15. Relator has standing to bring this action pursuant to 31 U.S.C. § 3730(b)(l).

16. Relator's complaint is not based on public disclosures of the allegations or transactions discussed herein within the meaning of 31 U.S.C. § 3730(e)(4)(A).

17. Relator, including through the knowledge of Whistleblower, is an original source of the information provided herein within the meaning of 31 U.S.C. § 3730(e)(4)(B).

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18. Prior to filing this action, Relator voluntarily disclosed to the United States the information on which the allegations or transactions discussed herein are based within the meaning of 31 U.S.C. § 3730(e)(4)(B).

C. Biofrontera

19. Defendant Biofrontera AG is an entity incorporated in Germany with its headquarters in Leverkusen, Germany.

20. Defendant Biofrontera Inc. is a corporation incorporated in Delaware which, upon information and belief, is the American subsidiary of Biofrontera AG.[1]

21. Defendants Biofrontera AG and Biofrontera Inc. are collectively referred to as "Biofrontera" herein unless otherwise distinguished.

22. As described further herein, Biofrontera is a pharmaceutical company that manufactures and distributes dermatological products in the European Union and the United States, including in the Western District of Washington.

III. JURISDICTION AND VENUE

23. Jurisdiction is founded under 31 U.S.C. § 3732(a) and (b), and 28 U.S.C. §§ 1331, 1345, and 1367(a).

24. Personal jurisdiction and venue are proper in the Western District of Washington pursuant to 28 U.S.C. §§ 1391(b) and 1395(a), and 31 U.S.C. § 3732(a), because Biofrontera transacts and has transacted business in the Western District of Washington.

IV. LEGAL AND REGULATORY BACKGROUND

A. The False Claims Act

25. The FCA "was passed in 1863 as a result of investigations of the fraudulent use of government funds during the Civil War." *United States v. Neifert-White Co.*, 390 U.S. 228, 232 (1968).

[1] All allegations in this complaint made "upon information and belief" are allegations that are "likely [to] have evidentiary support after a reasonable opportunity for further investigation or discovery" within the meaning of Rule 11(b)(3).

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26. The FCA "establishes a scheme that permits either the Attorney General or a private party to initiate a civil action alleging fraud on the Government," *U.S. ex rel. Eisenstein v. City of New York, New York*, 556 U.S. 928, 932 (2009) (citations omitted), and "imposes significant penalties on those who defraud the Government." *Universal Health Servs., Inc. v. United States*, 136 S. Ct. 1989, 1995 (2016).

27. The FCA provides, *inter alia*, that any person who (1) "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval," or (2) "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim," is liable to the United States for a civil monetary penalty plus treble damages. 31 U.S.C. § 3729(a)(1)(A)-(B).

28. The terms "knowing" and "knowingly" mean "that a person, with respect to information (1) has actual knowledge of the information; (2) acts in deliberate ignorance of the truth or falsity of the information; or (3) acts in reckless disregard of the truth or falsity of the information." 31 U.S.C. § 3729(b)(1)(A)(i)-(iii).

29. Proof of specific intent to defraud is not required. 31 U.S.C. § 3729(b)(1)(B).

30. The term "claim" means "any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that (1) is presented to an officer, employee, or agent of the United States; or (2) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest, and if the United States Government (a) provides or has provided any portion of the money or property requested or demanded; or (b) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded . . . ." 31 U.S.C. § 3729(b)(2)(A)(i)-(ii).

31. "[T]he term 'material' means having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4).

32. Pursuant to the Federal Civil Penalties Inflation Adjustment Act of 1990, as amended by the Debt Collection Improvement Act of 1996, 28 U.S.C. § 2461 and 64 Fed. Reg. 47099, 47103 (1999), the civil monetary penalties under the FCA are $5,500 to $11,000 for

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violations occurring on or after September 29, 1999, but before November 2, 2015. *See* 28 C.F.R. § 85.3.

33. Pursuant to the Federal Civil Penalties Inflation Adjustment Act Improvements Act of 2015 and 83 Fed. Reg. 706 (Jan. 8, 2018), the civil monetary penalties under the FCA were adjusted to $11,181 to $22,363 for violations occurring on or after November 2, 2015 that are assessed after January 29, 2018. *See* 28 C.F.R. § 85.5.

B. The Anti-Kickback Statute

34. The federal Anti-Kickback Statute ("AKS") makes it a criminal offense to "knowingly and willfully" offer, pay, solicit, or receive any remuneration to induce, or in return for, referrals of items or services paid for by a federal health care program. 42 U.S.C. § 1320a-7b. If any purpose of the remuneration is to induce or reward the referral or recommendation of business payable in whole or in part by a federal health care program, the AKS is violated, *i.e.*, a lawful purpose will not legitimize a remuneration that also has an unlawful purpose.

35. Specifically, the AKS provides:

> (1) Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—
>
> > (A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
> >
> > (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
>
> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $100,000 or imprisoned for not more than 10 years, or both.
>
> (2) Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—
>
> > (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or

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> (B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
>
> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $100,000 or imprisoned for not more than 10 years, or both.

42 U.S.C. § 1320a-7b(b)(1)-(2).

36. "Federal health care program" is defined as "(1) any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government (other than the health insurance program under chapter 89 of Title 5); or (2) any State health care program, as defined in section 1320a-7(h) of this title." 42 U.S.C. § 1320a-7b(f).

37. "Federal health care program" includes, *inter alia,* Medicare, Medicaid, and the Veterans Health Administration. *Id.*

38. While "[i]n some industries, it is acceptable to reward those who refer business to you," "in the Federal health care programs, paying for referrals is a crime."[2]

39. Violation of the AKS can subject the perpetrator to exclusion from participation in federal healthcare programs and civil monetary penalties of $50,000 per violation and three times the amount of remuneration paid. 42 U.S.C. § 1320a-7(b)(7); 42 U.S.C. § 1320a-7a(a)(7).

40. In addition, reimbursement claims to federal health care program that are tainted by violations of the AKS are false claims within the meaning of the FCA. 42 U.S.C. § 1320a-7b(g) ("In addition to the penalties provided for in this section or section 1320a-7a of this title, a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of subchapter III of chapter 37 of Title 31.").

C. Government Healthcare Programs

41. Title XVIII of the Social Security Act, 42 U.S.C. §§ 1395 *et seq.*, 42 U.S.C. §§ 426 and 426A, establishes the Health Insurance for the Aged and Disabled Program,

[2] HHS-OIG, *A Roadmap for New Physicians: Fraud & Abuse Laws*, available at https://oig.hhs.gov/compliance/physician-education/01laws.asp (last visited Apr. 26, 2021).

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popularly known as the Medicare program. Medicare is a government health insurance program for people age 65 or older, certain disabled people under age 65, and people of all ages with end stage renal disease. Medicare is comprised of four parts; Medicare Parts A through D.

42. Part A of the Medicare program authorizes payment for institutional care, including hospital, skilled nursing facility and home health care.

43. Medicare Part B, which is particularly relevant to the allegations raised herein, authorizes payment for physician and ancillary services, including laboratory and diagnostic tests and procedures. In addition, as particularly relevant in this action, Medicare Part B covers certain physician-administered drugs.

44. Medicare Part B is funded by insurance premiums paid by enrolled Medicare beneficiaries and contributions from the federal treasury. CMS contracts with private insurance companies to administer, process and pay Medicare Part B claims from the Federal Supplementary Medical Insurance Trust Fund. The private insurance companies that contract with CMS to provide these services are called Medicare Administrative Contractors, previously known as Medicare Part B carriers.

45. Part C of the Medicare program is also known as Medicare Advantage. Medicare Advantage Plans stand in place of Medicare Parts A and B and are offered by private companies approved by Medicare called Medicare Advantage Organizations. Medicare Advantage Plans may also offer prescription drug benefits ordinarily available under Medicare Part D. These plans are typically less expensive for the consumer, but limit covered beneficiaries to a network of covered providers.

46. Medicare Part D provides optional prescription drug coverage for Medicare beneficiaries. Unlike Medicare Part B coverage for physician-administered drugs, Medicare Part D typically covers self-administered drugs.

47. Throughout the relevant period, the services described herein were provided to beneficiaries of Medicare (including Medicare Advantage) and other federally and state funded healthcare programs (collectively referred to herein as "government payers" or "government insurers").

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V. FACTUAL BACKGROUND

A. Biofrontera and Ameluz

48. Biofrontera's leading product is Ameluz, which is FDA-approved to treat actinic keratoses on the face and scalp.

49. Actinic keratoses are precancerous lesions on the skin caused by overexposure to sunlight.[3]

50. Actinic keratoses typically appear on the parts of the human body that are most often exposed to sunlight, including the face, ears, scalp, hands, neck, and forearms. *Id.* at 16.

51. Actinic keratoses "occur most frequently in the elderly, especially elderly men, who are also at highest risk for death or disbursement form squamous cell cancer." *Id.* at 6.

52. If not treated successfully, actinic keratoses can progress to skin cancer. More specifically, actinic keratoses "are precursors of squamous cell cancers," a dangerous and often fatal form of skin cancer. *Id.*

53. There are a variety of treatment options for actinic keratoses, including cryotherapy and photodynamic therapy ("PDT").

54. Ameluz is a prescription topical gel that is used for PDT treatment of actinic keratoses.

55. PDT operates by topically applying a chemical agent to the area of the actinic keratosis(es), allowing the chemical agent to be absorbed into the skin, and then using a lamp to apply light to the area, which generates a photochemical reaction with the absorbed substance that is designed to destroy the damaged cells.[4]

---

[3] Mark Helfand et al., *Actinic Keratoses: Final Report* (May 19, 2001), available at https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/id1TA.pdf.

[4] Mark S. Nestor et al., *Safety and Efficacy of Aminolevulinic Acid 10% Topical Gel versus Aminolevulinic Acid 20% Topical Solution Followed by Blue-light Photodynamic Therapy for the Treatment of Actinic Keratosis on the Face and Scalp: A Randomized, Double-blind Study*, 12 J. CLINICAL & AESTHETIC DERMATOLOGY 32–38 (Mar 1, 2019), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6440706/.

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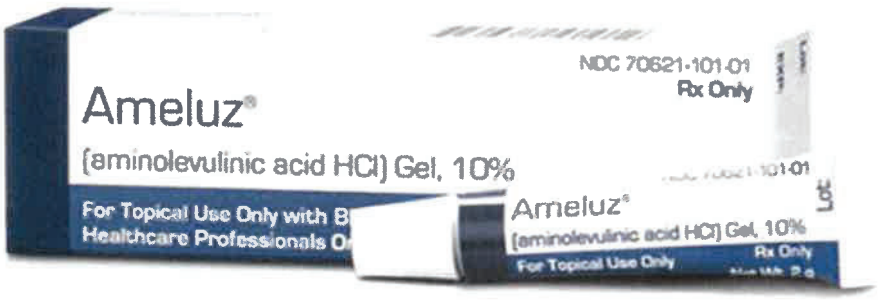
56. There are two types of light sources used in PDT treatment of actinic keratoses: blue light and red light.

57. The primary difference between the two types of light sources is that red light has a substantially longer wavelength than blue light. This difference has important clinical significance with respect to which type of light is appropriate to treat a particular patient's condition.

58. Moreover, the two chemical agents approved in the United States for PDT treatment of actinic keratoses are FDA-approved for different types of light sources. Ameluz, manufactured by Biofrontera, is approved as a red-light product. Levulan, manufactured by DUSA Pharmaceuticals, Inc. ("DUSA") and the primary competitor to Ameluz, is a blue-light product.

59. Ameluz is a provider-administered drug, meaning that it is administered directly by a provider (typically in an outpatient medical office), rather than by the patient (typically at home).

60. Ameluz is a topical-use gel that comes in a tube as pictured below:



61. A provider applies Ameluz topically to a patient's actinic keratoses and the surrounding area.

62. Following application of Ameluz, the provider covers the area with an occlusive dressing for several hours to allow the product to penetrate the patient's skin.

63. Pursuant to the FDA-approved instructions for Ameluz, the incubation period is intended to last for 3 hours.

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64. Following the incubation period, the occlusive dressing is removed and the provider uses a lamp to apply red light to the targeted area.

65. In addition to selling Ameluz, Biofrontera also sells the red-light lamp, which is known as BF-RhodoLED and costs approximately $7,500.

66. The process is pictured in the following graphic:[5]

67. Biofrontera initially launched Ameluz in the European Union and began selling Ameluz in the United States in or around October 2016.

68. The primary competitor to Ameluz in the United States is Levulan, manufactured by DUSA.

69. Collectively, Ameluz and Levulan control nearly the entire marketplace for PDT treatment of actinic keratoses in the United States.

70. While both are approved for the same treatment, the FDA-approved uses of Ameluz and Levulan differ in significant ways.

71. Most significantly for purposes of this action and as noted above, the two products used different types of light sources: Ameluz is approved for use with a red-light source.

72. In addition, the FDA-approved incubation period for Ameluz is 3 hours, while the FDA-approved incubation period for Levulan is 3 hours for actinic keratoses on the upper extremities but 14-18 hours for actinic keratoses on the face or scalp.

[5] Biofrontera, *Using BF-RhodoLED*, available at http://www.biofrontera.us.com/using-bf-rhodoled/ (last visited Apr. 26, 2021).

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73. Levulan launched in the United States in 1999 and, with only modest interruptions, enjoyed a monopoly in the United States with respect to PDT treatment of actinic keratoses.

74. By the time Biofrontera began marketing Ameluz in the United States in late 2016, Levulan had been available in the United States for nearly two decades, making it exceptionally difficult for Biofrontera to gain market share.

75. In addition, commercial success in the United States is critical to Biofrontera's financial vitality, as sales in the United States already account for the majority of Biofrontera's global sales, notwithstanding that Biofrontera has only distributed its products in the United States since late 2016.

76. For these reasons, Biofrontera launched, and continues to employ, an aggressive strategy to attempt to compete against Levulan and to gain market share in the United States as quickly as possible. These aggressive efforts include the kickbacks at issue in this lawsuit.

B. Coverage by Government Healthcare Programs for Ameluz

77. Generally speaking, government healthcare programs, including Medicare, cover treatment options for actinic keratoses, subject to various conditions and limitations.[6]

78. Medicare, through Medicare Part B and Medicare Advantage, is the most significant government payor because most actinic keratosis patients receive healthcare coverage through Medicare, which is largely attributable to the fact that Medicare-eligible older Americans are disproportionately affected by actinic keratoses.[7]

[6] CMS, *Decision Memo for Actinic Keratoses* (July 19, 2001), available at https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=1.

[7] Actinic keratosis (AK) was the most common dermatologic diagnosis among all dermatologist visits in the United States for patients 45 years or older during the period from 1993 to 2010. Howa Yeung et al., *Use and Cost of Actinic Keratosis Destruction in Medicare Part B Fee-for-Service Population, 2007 to 2015*, 154 JAMA DERMATOLOGY 1281–1285 (Nov. 2018), available at https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6248125/.

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79. It is estimated that 52-60% of actinic keratosis patients are Medicare beneficiaries.[8]

80. Providers bill for PDT treatment in two components: (a) billing for the topical gel used during the process, *i.e.*, Ameluz or Levulan, and (2) billing for performance of the PDT procedure itself.

81. As to the first category, Medicare generally covers provider-administered drugs like Ameluz on a "buy and bill" basis, meaning that a provider must first purchase the drug and then bill for it after it is administered.[9]

82. Given this reimbursement model, providers accept the risk that the drug will not actually be administered or that reimbursement will be denied. In either case, a provider is not reimbursed for a product for which they have already paid. In other words, providers are forced to accept the risk of not receiving reimbursement, a particularly significant concern given the high cost of many provider-administered drugs.

83. Providers bill for provider-administered drugs like Ameluz by using so-called J-Codes.

84. Certain products have product-specific J-Codes, while others do not and are billed using "unclassified" or "miscellaneous" J-Codes.

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[8] Lindsey Warino et al., *Frequency and cost of actinic keratosis treatment*, 32 DERMATOLOGIC SURGERY 1045–1049 (Aug. 2006), available at https://pubmed.ncbi.nlm.nih.gov/16918567/ ("There are an estimated 5.2 million AK visits annually, 60% of which are made by the Medicare population."); Yeung, *supra* note 7 ("Destructive procedures—including cryotherapy, curettage, electrocautery, and chemical peels—were performed in 77% of 5.2 million dermatologist visits for AK management in 2000-2003, 52% of which were performed in Medicare populations.").

[9] *See United States v. Regeneron Pharm., Inc.*, 2020 WL 7130004, at *1 (D. Mass. Dec. 4, 2020) (describing that a buy and bill drug means "means that physicians buy the drug in bulk and store it in their offices before prescribing and administering it to patients, filing a claim with Medicare … and receiving reimbursement"); *Bolling v. Dendreon Corp.*, 2014 WL 12042559, at *2 (W.D. Wash. Jan. 28, 2014) ("Under this model, the treating physician makes an up-front payment for [the product] then later seeks reimbursement from the patient's private insurer or from Medicare").

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85. Obtaining a product-specific J-Code is important for the commercial success of a product that is billed on a buy-and-bill basis. This is because the use of a miscellaneous J-Code frequently leads to the payor (such as Medicare) requesting additional information, imposing a significant administrative burden on providers. In addition, the use of a miscellaneous J-Code substantially increases the likelihood that reimbursement will be denied.

86. In November 2017, at Biofrontera's request, CMS announced that it was adopting a product-specific J-Code for Ameluz. The new J-Code, J7345, became effective for Ameluz administered on or after January 2, 2018. This J-Code is now generally used to bill all payors, including Medicare Part B, Medicare Advantage, and other government and commercial payors.

87. Prior to issuance of the product-specific J-Code for Ameluz, providers billed for Ameluz using miscellaneous J-Codes.

88. Upon information and belief, the Medicare Part B reimbursement rate for Ameluz in 2019 and 2020 (using J-Code J7345) was approximately $1.50/10 mg. A standard tube of Ameluz contains 2,000 mg, and consequently, the use of an entire tube of Ameluz would allow billing of 200 units and the overall reimbursement for a 2,000 mg tube was approximately $300 in 2019.

89. Upon information and belief, Medicare Advantage plans cover Ameluz in a similar amount as Medicare Part B.

90. In addition to reimbursement for Ameluz, providers are separately reimbursed for performance of the PDT procedure.

91. Providers bill for performance of the PDT procedure using one of the following current procedural terminology ("CPT") codes:

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Code	Description	Medicare National Payment Amount (2020)[10]
96574	Debridement of premalignant hyperkeratotic lesion(s) (*i.e.*, targeted curettage, abrasion) followed with photodynamic therapy by external application of light to destroy premalignant lesions of the skin and adjacent mucosa with application and illumination/activation of photosensitizing drug(s) provided by a physician or other qualified health care professional, per day	$273.56
96573	Photodynamic therapy by external application of light to destroy premalignant lesions of the skin and adjacent mucosa with application and illumination/activation of photosensitizing drug(s) provided by a physician or other qualified health care professional, per day	$217.62
96567	Photodynamic therapy by external application of light to destroy premalignant and/or malignant lesions of the skin and adjacent mucosa (e.g., lip) by activation of photosensitive drug(s), each phototherapy exposure session	$136.06

VI. BIOFRONTERA'S NATIONWIDE KICKBACK AND OFF-LABEL MARKETING SCHEME

92. Biofrontera engaged in a systematic, multifaceted, and nationwide kickback and off-label marketing scheme in an illegal effort to gain market share for Ameluz.

A. The Kickback Scheme

93. Providers typically purchase Ameluz in orders of 5 or 10 tubes at an average price of approximately $299/tube.

94. Less frequently, providers place orders for 20 or more tubes of Ameluz, which result in a bulk purchasing discount of $294/tube.

95. Given that the average reimbursement for Ameluz is approximately $300/tube, there is very little, if any, profit margin for providers on the supply side of reimbursement. However, as described above, providers are separately reimbursed for performance of PDT therapy.

[10] This reflects the national payment amount. The reimbursement amount received by a particular provider is adjusted based on their locality.

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96. When a provider orders 10 tubes of Ameluz, Biofrontera frequently provides 2 additional tubes for free, ostensibly as "training tubes." In doing so, the effective price paid by the provider drops from $299/tube to about $249/tube.

97. Biofrontera also often (but less frequently) provides free tubes when a provider places a smaller order, and there is no required threshold to obtain free product.

98. Thus, even though the 5-tube and 10-tube price is ostensibly the same, providers are strongly incentivized to purchase at least 10 tubes of Ameluz so that they can receive free tubes. Likewise, sales representatives strongly push providers to order at least 10 tubes so that they can earn a higher commission.

99. If a provider orders more than 10 tubes of Ameluz, Biofrontera will give an even higher number of free tubes.

100. For example, when a provider orders 20 tubes of Ameluz, Biofrontera typically gives the provider 5 free tubes.

101. These free products are particularly valuable to providers given that, as described above, Ameluz is reimbursed on a "buy and bill" basis under which providers must first purchase a product and can only seek reimbursement if the product is actually administered, thus accepting the risk that the product will not be administered or that reimbursement will be denied.

102. Thus, by providing free tubes of Ameluz, Biofrontera is eliminating the cost to providers, in addition to allowing them to generate a 100% profit on any free product that is used.[11]

103. In addition to giving providers free Ameluz generally, a second component of the kickback scheme is that Biofrontera gives providers free tubes of Ameluz when reimbursement is denied, which provides another valuable kickback to providers.

[11] *See* Cole Werble, *Health Policy Brief: Medicare Part B*, HEALTH AFFAIRS (Aug. 10, 2017), available at https://www.healthaffairs.org/do/10.1377/hpb20171008.000171/full/ ("Part B uses a reimbursement or buy-and-bill model, meaning that providers purchase the drug first, then bill for it after it is administered. Given that some Part B drugs are quite expensive, the certainty of the reimbursement and the attractive add-on handling fee . . . are important considerations for providers.").

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104. Payors, such as Medicare and commercial insurers, routinely deny reimbursement for a wide variety of reasons.

105. The reasons that a reimbursement claim can be denied include both substantive problems (such as that the service or product for which reimbursement is sought was deemed medically unnecessary) and procedural issues (such as that the provider did not include required information in the claim or included incorrect or invalid information).

106. A denied claim for a "buy and bill" product like Ameluz is particularly undesirable for providers given that they already paid for the product and now will not receive any reimbursement for it.

107. To offset the harm to providers, Biofrontera provides free tubes of Ameluz when a provider's reimbursement claim for Ameluz is denied, including with respect to Medicare claims. This includes 5-tube orders which, as described above, are excluded from the broader kickback scheme.

108. In this way, Biofrontera provides a valuable guarantee to providers that they will either (a) be reimbursed for their use of Ameluz or (b) receive an additional tube of Ameluz whenever reimbursement is denied for whatever reason.

109. The provision of free tubes of Ameluz generates major profit for providers.

110. Medicare Part B reimburses for prescription drugs on the basis of the drug's Average Sales Price ("ASP").

111. Generally speaking, the reimbursement amount is 106% of a drug's ASP, *i.e.* ASP + 6%.[12]

[12] *See* MedPAC, *Improving Medicare's payment for Part B drugs: Requiring pharmaceutical manufacturer reporting of sales price data* (Jun. 14, 2019), available at http://www.medpac.gov/-blog-/requiring-reporting-of-sales-price-data/2019/06/14/payment-for-part-b-drugs ("Medicare pays providers 106 percent of a manufacturer's average sales price (ASP) (i.e., 100 percent of the ASP plus a 6 percent add-on) for a drug, regardless of the price a given provider actually pays for the product.").

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112. Thus, if the ASP for a full tube of Ameluz is approximately $300, a physician could typically expect to receive approximately $318/tube. This provides a profit of $18 to the physician.

113. On the other hand, if the physician pays $0 for a "training tube" of Ameluz and bills Medicare Part B for it, the physician will receive the same reimbursement of $318/tube but will have realized a profit of $318.

114. Thus, Biofrontera's provision of free Ameluz allows physicians to generate substantial profits, *e.g.*, an increased profit of $300 in the example above.

115. As described further below, it is illegal to bill Medicare for free samples.[13]

B. The Off-Label Marketing Scheme

116. In tandem with the above-described kickback scheme, Biofrontera also promoted the off-label use of Ameluz and indeed, knowingly distributed Ameluz to physicians who *could only utilize* Ameluz for off-label uses.

117. As described above, by the time Ameluz was launched in the United States in late 2016, Levulan had been available in the United States for nearly two decades and enjoyed a near monopoly for PDT treatment of actinic keratoses.

118. Consequently, Biofrontera was forced to target current users of Levulan, *i.e.* attempt to convert current Levualn users to Ameluz users.

119. This posed a significant problem with respect to Biofrontera's efforts to capture market share because Levulan is FDA-approved as a blue-light product, while Ameluz is FDA-approved as a red-light product.

120. More specifically, Ameluz is only FDA-approved for use with BF-RhodoLED, a red-light lamp manufactured by Biofrontera. Exhibit A at 2 (FDA product label for Ameluz providing: "AMELUZ® gel, in combination with photodynamic therapy (PDT) *using BF-*

[13] *See* HHS-OIG, *A Roadmap for New Physicians: III. Physician Relationships With Vendors*, available at https://oig.hhs.gov/compliance/physician-education/04vendors.asp (last visited Apr. 19, 2021) ("It is legal to give these samples to your patients for free, but it is illegal to sell the samples. The Government has prosecuted physicians for billing Medicare for free samples.").

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RhodoLED® lamp, a narrowband, red light illumination source, is indicated for lesion-directed and field-directed treatment of actinic keratoses . . . PDT *requires administration of both AMELUZ and BF-RhodoLED light.*") (emphases added).

121. The heat lamps that are approved for use with Ameluz and Levulan are very expensive. For example, the retail price of Biofrontera's BF-RhodoLED is $7,500. Consequently, most providers do not have both red-light and blue-light lamps and are financially disincentivized from purchasing a new heat lamp if, for example, they want to switch from a blue-light product like Levulan to a red-light product like Ameluz.

122. Thus, when Biofrontera gave free Ameluz to providers who typically use Levulan, most providers could only use Ameluz with their existing blue-light lamp.

123. Ameluz is only FDA-approved for use with the BF-RhodoLED lamp. Ameluz is not FDA-approved for use with any other red-light lamp, nor with any blue-light lamp.

124. Nonetheless, in an effort to capture market share, Biofrontera told Levulan users that they could and should use Ameluz with their existing blue-light lamps, such that purchasing an expensive BF-RhodoLED red-light lamp was unnecessary.

125. Biofrontera told physicians to simply replace Levulan with Ameluz without replacing their blue-light lamps, notwithstanding that Ameluz is only FDA-approved for use with BF-RhodoLED red-light lamps.

126. Biofrontera *knows* which physicians do and do not have BF-RhodoLED red-light lamps because Biofrontera is the *only* company that manufactures and distributes these lamps in the United States.

127. As such, Biofrontera knows when it is selling Ameluz to a physician whether the physician has a BF-RhodoLED red-light lamp.

128. Nonetheless, Biofrontera routinely sells Ameluz to physicians who do not have BF-RhodoLED have red-light lamps, primarily consisting of physicians who had been using Levulan and thus only have blue-light lamps.

129. Relator does not recall a single instance where Biofrontera stopped selling Ameluz to a physician who did not have a BF-RhodoLED red-light lamp.

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130. As described above, Biofrontera did more than knowingly *distribute* Ameluz to providers who it knew did not have BF-RhodoLED red-light lamps; it also knowingly *promoted* and *encouraged* the use of Ameluz on other lamps, including blue-light lamps.

131. The usage of Ameluz with unapproved blue lights is widespread, and Relator estimates that *75-80%* of physicians in his territory (Virginia, Maryland, and Washington D.C.) were using Ameluz with blue-light lamps during his time at Biofrontera.

132. Relator provides the following representative examples of practitioners in his region that purchased and used Ameluz but did *not* own BF-RhodoLED red-light lamps:

- Mid-Atlantic Skin Surgery Institute in Waldorf, MD, which only had a blue-light lamp but purchased Ameluz in, *inter alia*, October 2018, April 2019, November 2019, and June 2020.
- Herndon Dermatology in Herndon, VA, which only had a blue-light lamp but purchased Ameluz in, *inter alia*, October 2019, November 2019, and February 2020.
- Liotta Dermatology in Frederick, MD, which only had a blue-light lamp but purchased Ameluz in, *inter alia*, February 2020 and May 2020.
- DSF Cosmetic and Medical Dermatology in Frederick, MD, which only had a blue-light lamp but purchased Ameluz in, *inter alia*, September 2019, November 2019, and January 2020.

133. As illustrated by these representative examples, Biofrontera sold Ameluz to practitioners consistently over a long period despite knowing that they did not have BF-RhodoLED red-light lamps and instead were using Ameluz, in violation of the FDA-approved instructions, with unapproved blue-light lamps.

134. In addition to promoting the off-label use of Ameluz with blue-light lamps, Biofrontera exacerbated the risk for patient harm by telling providers that they should continue utilizing the same incubation period for Ameluz as they did with Levulan even though Biofrontera knew that many providers were using incubation periods that were significantly shorter than the FDA-approved incubation periods.

135. The FDA-approved product label for Ameluz provides for an incubation period of 3 hours.

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136. The FDA-approved product label for Levulan provides for an incubation period of 3 hours for actinic keratoses on the upper extremities, while providing for a 14-18 hour incubation period for actinic keratoses on the face or scalp.

137. The longer the incubation period, the more resources a provider must utilize for PDT treatment, and the fewer treatments that a provider can provide in a day. Thus, providers have a financial and resource-driven motivation to utilize shorter incubation periods notwithstanding the FDA-approved instructions.

138. The utilization of incubation periods that are significantly shorter than the FDA-approved instructions for use is a well-known problem in the industry.

139. For example, the Government recently settled a $20.75 million False Claims Act case against DUSA based on allegations that DUSA knowingly encouraged providers to use short 1-3 hour incubation periods for Levulan even though DUSA knew that doing so would result in a far less effective treatment of actinic keratoses and even though the FDA-approved instructions required use of a 14-18 hour incubation period.[14]

140. As part of their effort to have providers switch from Levulan to Ameluz, Biofrontera told providers that they should continue to use the same incubation periods for Ameluz as they were for Levulan notwithstanding that (a) many providers utilized incubation periods of significantly less than 3 hours for Levulan and (b) the FDA-approved instructions for use for Ameluz required a 3-hour incubation period.

141. In other words, as above with the usage of Ameluz on unapproved blue-light lamps, Biofrontera told providers to maintain the same practices they used with Levulan even though such practices were not in accord with the FDA-approved instructions.

142. Utilizing the appropriate incubation period is vital to ensure effective treatment of actinic keratoses.

[14] Department of Justice, *DUSA Pharmaceuticals To Pay U.S. $20.75 Million To Settle False Claims Act Allegations Relating To Promotion Of Unsupported Drug Administration Process* (Aug. 24, 2020), available at https://www.justice.gov/opa/pr/dusa-pharmaceuticals-pay-us-2075-million-settle-false-claims-act-allegations-relating.

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143. For example, the above-described settlement agreement with DUSA included allegations "that DUSA failed to inform physicians that administering the drug using short incubation periods resulted in significantly lower AK clearance rates than achieved with the longer incubation period described in the FDA-approved instructions, and, in some instances, the company falsely stated that AK clearance rates were the same for the shorter and less effective incubation periods."[15]

144. In these ways, Biofrontera knowingly promoted and encouraged the off-label use of Ameluz.

C. Operation and Nationwide Scope of Scheme

145. Biofrontera's kickback and off-label marketing schemes were centrally orchestrated by Biofrontera's senior management and occurred nationwide.

146. Through discussions with sales representatives, Relator has been directly told that Biofrontera's kickback and off-label marketing schemes are nationwide.

147. Senior management directed sales representatives to (1) promote the free tubes of Ameluz to providers as an incentive for purchasing at least 10 tubes and (2) carry out the necessary administrative functions to implement the scheme, such as by inputting orders in Biofrontera's electronic sales platform.

148. The instructions from senior management were verbally communicated and never memorialized in writing.

149. Such instructions would typically be delivered down the chain of command from regional sales managers to territory sales managers to sales representatives.

150. For example, Relator was instructed to engage in the kickback scheme by Mark Baldyga, a regional sales manager who was Relator's direct supervisor.

151. Mr. Baldyga supervised sales in Biofrontera's southeast region, which included Relator's territory in Washington D.C., Maryland, and Virginia.

[15] *Id.*

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152. Mr. Baldyga also supervised seven other territory managers in a region that spanned from Washington D.C. to Florida. Mr. Baldyga remains in this role at Biofrontera.

153. Mr. Baldyga directly instructed Relator to engage in the kickback scheme, including that the sales representative should be instructed to promote the free tubes of Ameluz to providers as an incentive for purchasing at least 10 tubes. Mr. Baldyga would tell Relator this during one-on-one phone calls.

154. Likewise, Mr. Baldyga instructed Relator to tell Levulan users to "continue doing what you're doing" with respect to both (1) using an unapproved blue-light machine for Ameluz and (2) using a shorter incubation period that violated the FDA-approved instructions for Ameluz.

155. During Relator's time at Biofrontera, there were five other regional sales managers at Mr. Baldyga's level, each of whom managed a geographic region of territory managers and sales representatives.

156. In addition to the instructions Relator received from Mr. Baldyga, he received similar instructions through his initial training when he first joined Biofrontera in January 2018.

157. Relator's training was conducted in Biofrontera's Massachusetts office by Jeff Holm, who remains an employee of Biofrontera.

158. Relator trained with two other new sales representatives, who were subsequently assigned to Biofrontera's Midwest (including Ohio) and Northeast (including Pennsylvania) sales regions.

159. During training, Mr. Holm provided the same instructions that Relator would later hear from Mr. Baldyga, *i.e.*, to provide free Ameluz as a kickback and to promote the off-label use of Ameluz.

160. During training with Mr. Holm, and then through Mr. Baldyga, Relator was consistently instructed that the most important goal was to sell the product (Ameluz) and to gain market share against Levulan.

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161. While Biofrontera wanted to sell the red-light lamp to physicians as well, given that the red-light lamp costs approximately $7,500, most physicians did not want to purchase it, particularly those who already invested in a blue-light lamp for use with Levulan.

162. In those instances, Relator was trained by Mr. Holm and subsequently instructed by Mr. Baldyga to sell Ameluz and to assure the physicians that they could and should keep doing what they had been doing with Levulan even though, as described above, this promoted the off-label use of Ameluz.

163. Based on Relator's training and experience at Biofrontera, the company utilizes the same sales practices and procedures across the country.

D. Representative Examples of Kickback Scheme

164. Relator provides the following representative examples of doctors who repeatedly received free units of Ameluz from Biofrontera in return for purchasing Ameluz.

165. The free units identified below are described in Biofrontera's sales management platform—which Relator regularly used during his time at Biofrontera—as "training tubes."

166. Dr. Saif Syed works at a dermatology practice in Lutherville, Maryland. As shown below, Biofrontera routinely gave free units of Ameluz to Dr. Syed:

Order Number	Date	Units of Ameluz	Paid or Free?
SO-1450	September 27, 2017	4	Free
SO-1494	September 30, 2017	5	Paid
SO-2197	December 1, 2017	5	Free
SO-2500	December 27, 2017	100	Paid
SO-3150	February 21, 2018	5	Free
SO-6306	November 19, 2018	2	Free
SO-6525	December 5, 2018	24	Paid
SO-6953	January 8, 2019	24	Paid
SO-7140	January 16, 2019	50	Paid
SO-7162	January 16, 2019	5	Free
SO-7907	March 11, 2019	10	Paid
SO-8272	March 29, 2019	25	Paid
SO-8685	May 2, 2019	20	Paid
SO-9190	June 18, 2019	20	Paid
SO-9702	August 21, 2019	20	Paid
SO-10151	October 1, 2019	20	Paid
SO-11695	December 19, 2019	5	Free

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Order Number	Date	Units of Ameluz	Paid or Free?
SO-12824	March 11, 2020	2	Free
SO-12847	March 12, 2020	100	Paid
SO-13055	May 15, 2020	2	Free

167. Dr. Maithily Nandedkar works at a dermatology practice in Reston, Virginia. As shown below, Biofrontera routinely gave free units of Ameluz to Dr. Nandedkar:

Order Number	Date	Units of Ameluz	Paid or Free?
SO-3090	February 16, 2018	2	Free
SO-6535	December 6, 2018	5	Paid
SO-6584	December 7, 2018	5	Paid
SO-7256	January 23, 2019	5	Paid
SO-7382	February 1, 2019	2	Free
SO-8254	March 28, 2019	5	Paid
SO-8319	April 2, 2019	2	Free
SO-9050	June 4, 2019	5	Free
SO-9134	June 12, 2019	2	Free
SO-9679	August 20, 2019	5	Paid
SO-9926	September 16, 2019	2	Free
SO-9911	September 16, 2019	5	Paid
SO-10348	October 15, 2019	5	Paid
SO-10544	October 25, 2019	5	Paid
SO-10954	November 14, 2019	5	Paid
SO-11459	December 11, 2019	20	Paid
SO-11545	December 13, 2019	2	Free

168. As illustrated by these representative examples, Biofrontera consistently provides "training tubes" of Ameluz long after the provider has begun using Ameluz. This demonstrates that these were not used for bona fide training purposes or as bona fide product samples allowing a provider to test a new product, but rather pure kickbacks to generate additional revenue for the provider and reward the provider for continuing to purchase Ameluz.

169. Based on Relator's experience at Biofrontera and his discussion with other employees, including sales representatives at Biofrontera, these examples are emblematic and representative of Biofrontera's customary practices across the country.

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VII. BIOFRONTERA'S FALSE CLAIMS ACT LIABILITY

170. 31 U.S.C. § 3729(a)(1)(A) prohibits "knowingly present[ing], or caus[ing] to be presented, a false or fraudulent claim for payment or approval."

171. 31 U.S.C. § 3729(a)(1)(B) prohibits "knowingly mak[ing], us[ing] or caus[ing] to be made or used, a false record or statement material to a false or fraudulent claim."

172. "Claim" is defined as including "any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property, that (1) is presented to an officer, employee, or agent of the United States; or (2) is made to a contractor, grantee, e, or other recipient, if the money or property is to be spent or used on the Governments behalf or to advance a Government program or interest, and if the United States Government (a) provides or has provided any portion of the money or property requested or demanded; or (b) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded . . . ." 31 U.S.C. § 3729(b)(2)(A)(i)-(ii).

173. Based on the illegal conduct described above, Biofrontera is subject to liability under the FCA under 31 U.S.C. § 3729(a)(1)(A) and 31 U.S.C. § 3729(a)(1)(B).

174. In violation of 31 U.S.C. § 3729(a)(1)(A), Biofrontera caused the presentation of false claims by causing the presentation of reimbursement claims for Ameluz that were tainted by Biofrontera's kickbacks in violation of the AKS.

175. Reimbursement claims to government payors that are tainted by AKS violations are false for at least two reasons: (1) the AKS specifically so provides and (2) such claims violate the certifications made by providers when submitting claims.

176. The AKS provides that "a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of subchapter III of chapter 37 of Title 31." 42 U.S.C. § 1320a-7b(g).

177. Providers submit claims for reimbursement for medical services and equipment by using CMS Form 1500 or its electronic equivalent.

178. The provider must sign the form (field number 31) and attest to the certifications found on the reverse side of CMS Form 1500.

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179. These certifications include the following relevant statements (with added emphasis):

> In submitting this claim for payment from federal funds, I certify that: 1) the information on this form is true, accurate and complete; 2) I have familiarized myself with all applicable laws regulations, and program instructions, which are available from the Medicare contractor; 3) I have provided or will provide sufficient information required to allow the government to make an informed eligibility and payment decision; 4) *this claim, whether submitted by me or on my behalf by my designated billing company, complies with all applicable Medicare and/or Medicaid laws, regulations, and program instructions for payment including but not limited to the Federal anti-kickback statute and Physician Self-Referral law (commonly known as Stark law);* 5) the services on this form were medically necessary and personally furnished by me or were furnished incident to my professional service by my employee under my direct supervision, except as otherwise expressly permitted by Medicare or TRICARE; 6) for each service rendered incident to my professional service, the identity (legal name and NPI, license#, or SSN) of the primary individual rendering each service is reported in the designated section.

180. Thus, if a claim does not "compl[y] with . . . the Federal anti-kickback statute," the certification is false.

181. In violation of 31 U.S.C. § 3729(a)(1)(B), Biofrontera caused the creation and use of false records that are material to false claims when, *inter alia*, it caused providers to falsely certify compliance with applicable federal laws, specifically including the AKS.

182. Furthermore, Biofrontera's kickback violations also caused providers to submit false claims in violation of 31 U.S.C. § 3729(a)(1)(A) by causing providers to submit claims in violation of Medicare's prohibition against seeking reimbursement for "no cost" items such as free samples. *See* U.S.C.A. § 1395y(a)(2).

183. The Medicare Claims Processing Manual providers:

> On occasion, providers may receive an item (such as a device or drug) that is offered by a manufacturer/supplier free of charge. Such items, for purposes of these instructions, are considered "no cost items." Providers are not to seek reimbursement for no cost items as noted in Section 1862(a)(2) of the Social Security Act [§ 1395y(a)(2].

Medicare Claims Processing Manual, ch. 32 § 67.

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184. A company "causes" the presentment of false claims when its conduct is a proximate cause of the false claim. *See United States v. Marder*, 208 F. Supp. 3d 1296, 1312 (S.D. Fla. 2016) ("Although the FCA does not define the phrase 'cause to be presented,' courts have applied traditional concepts of proximate causation to determine whether there is a sufficient nexus between the Defendants' conduct and the ultimate presentation of the alleged false claim.").

185. Through the above-described conduct, Biofrontera caused physicians to submit false claims for Medicare reimbursement for free Ameluz, and such reimbursement claims were the direct, foreseeable, and intended consequence of Biofrontera's conduct.

186. In addition to its kickback-based violations, Biofrontera's encouragement to providers to use Ameluz for off-label uses in violation of the FDA-approved instructions independently violates the FCA.

187. As described above, Biofrontera promoted the off-label use of Ameluz by encourage physicians to use Ameluz with unapproved blue-light lamps and utilizing an incubation period significantly shorter than the FDA-approved incubation period.

VIII. CLAIMS

COUNT I

VIOLATION OF THE FALSE CLAIMS ACT – 31 U.S.C. §3729(A)(1)(A)

188. Relator repeats and re-alleges each and every allegation contained in the paragraphs above as though fully set forth herein.

189. In violation of 31 U.S.C. § 3729(a)(1)(A), Biofrontera knowingly presented or caused the presentment of false or fraudulent claims for payment or approval to (1) officials of the United States and/or (2) contractors, grantees, or other recipients of money provided by or that would be reimbursed by the United States.

190. The false statements made by Biofrontera had a natural tendency to influence or be capable of influencing the payment of the claims, and in fact, did influence the payment of the claims.

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191. Biofrontera made fraudulent and false statements with actual knowledge of the falsity of its statements, with deliberate ignorance of the falsity of its statements, or with reckless disregard as to the falsity of its statements.

192. By virtue of the false or fraudulent claims that Biofrontera presented or caused to be presented, the United States has suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

COUNT II

VIOLATION OF THE FALSE CLAIMS ACT – 31 U.S.C. §3729(A)(1)(B)

193. Relator repeats and re-alleges each and every allegation contained in the paragraphs above as though fully set forth herein.

194. In violation of 31 U.S.C. § 3729(a)(1)(B), Biofrontera knowingly made, used, or caused to be made or used, false records or statements material to false or fraudulent claims to (1) the United States or (2) contractors, grantees, or other recipients of money provided by or that would be reimbursed by the United States.

195. The false records and statements made by Biofrontera had a natural tendency to influence or be capable of influencing the payment of the claims, and in fact, did influence the payment of the claims.

196. By virtue of the false records and statements made by Biofrontera, the United States has suffered actual damages and is entitled to recover treble damages and a civil penalty for each false claim.

PRAYER FOR RELIEF

WHEREFORE, Relator, on behalf of the United States, demands that judgment be entered in their favor and against Biofrontera for:

A. Three times the amount of damages to the United States;

B. Civil penalties of (a) $5,500-$11,000 for each violation of the FCA that occurred after September 29, 1999, but before November 2, 2015, and (b) $11,181-$22,363 for each violation of the FCA that occurred on or after November 2, 2015;

C. Any other recoveries or relief provided for under the FCA;

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D. Relators' receipt of the maximum amount permitted by law of the proceeds of this action or settlement of this action collected by the United States, plus reasonable expenses necessarily incurred, and reasonable attorneys' fees and costs, based upon the total value recovered, both tangible and intangible, including any amounts received from individuals or entities not parties to this action; and

E. Such other relief as the Court may deem appropriate.

DEMAND FOR JURY TRIAL

Pursuant to Federal Rule of Civil Procedure 38, Relator hereby demands a trial by jury.

DATED this 28th day of April, 2021.

Respectfully submitted,

HAGENS BERMAN SOBOL SHAPIRO LLP

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Exhibit A

HIGHLIGHTS OF PRESCRIBING INFORMATION

These highlights do not include all the information needed to use AMELUZ safely and effectively. See full prescribing information for AMELUZ.

AMELUZ® (aminolevulinic acid hydrochloride) gel, 10%, for topical use
Initial U.S. approval: 1999

INDICATIONS AND USAGE

AMELUZ gel, a porphyrin precursor, in combination with photodynamic therapy using BF-RhodoLED lamp, is indicated for the lesion-directed and field-directed treatment of actinic keratoses of mild-to-moderate severity on the face and scalp (1).

DOSAGE AND ADMINISTRATION

- Administer AMELUZ only by a health care provider (2.1).
- AMELUZ is for topical use only (2.1).
- Photodynamic therapy with AMELUZ involves preparation of lesions, application of the product, occlusion and illumination with BF-RhodoLED (2.2).
- Retreat lesions that have not completely resolved 3 months after the initial treatment (2.2).
- See BF-RhodoLED user manual for detailed lamp safety and operating instructions (2).

DOSAGE FORMS AND STRENGTHS

Gel: 10% (3).

CONTRAINDICATIONS

- Known hypersensitivity to porphyrins (4).
- Known hypersensitivity to any component of AMELUZ, which includes soybean phosphatidylcholine (4).
- Porphyria (4).
- Photodermatoses (4).

WARNINGS AND PRECAUTIONS

- *Risk of Eye Injury:* Patients and healthcare providers must wear protective eyewear before operating BF-RhodoLED lamp (5.1).
- *Photosensitivity:* Protect treated lesions from sunlight exposure for 48 hours post treatment (5.2).
- *Risk of Bleeding:* Special care should be taken to avoid bleeding during lesion preparation in patients with inherited or acquired coagulation disorders (5.3).
- *Ophthalmic Adverse Reactions:* Avoid direct contact of AMELUZ with the eyes (5.4).
- *Mucous Membranes Irritation:* Avoid direct contact of AMELUZ with the mucous membranes (5.5).

ADVERSE REACTIONS

Most common adverse reactions (≥ 10%) were application site erythema, pain/burning, irritation, edema, pruritus, exfoliation, scab, induration, and vesicles (6.1).

To report SUSPECTED ADVERSE REACTIONS, contact Biofrontera Inc. at 1-884-829-7434 or FDA at 1-800-332-1088 or www fda.gov/medwatch.

DRUG INTERACTIONS

Concomitant use of the following medications may enhance the phototoxic reaction to photodynamic therapy: St. John's wort, griseofulvin, thiazide diuretics, sulfonylureas, phenothiazines, sulphonamides, quinolones, and tetracyclines (7).

See 17 for PATIENT COUNSELING INFORMATION

Revised: 05/2016

FULL PRESCRIBING INFORMATION: CONTENTS*

*Sections or subsections omitted from the full prescribing information are not listed

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FULL PRESCRIBING INFORMATION

1. INDICATIONS AND USAGE

AMELUZ® gel, in combination with photodynamic therapy (PDT) using BF-RhodoLED® lamp, a narrowband, red light illumination source, is indicated for lesion-directed and field-directed treatment of actinic keratoses (AKs) of mild-to-moderate severity on the face and scalp.

2. DOSAGE AND ADMINISTRATION

2.1 Important Administration Information

AMELUZ, in conjunction with lesion preparation, is only to be administered by a health care provider.

AMELUZ is for topical use only. Not for ophthalmic, oral, or intravaginal use.

Treat single lesions or an entire field affected by multiple lesions with AMELUZ, in combination with red light photodynamic therapy (PDT). PDT requires administration of both AMELUZ and BF-RhodoLED light. Retreat lesions that have not completely resolved after 3 months after the initial treatment.

Refer to BF-RhodoLED user manual for detailed lamp safety and operating instructions. Both patient and medical personnel conducting the PDT should adhere to all safety instructions.

2.2 Dosage and Administration Instructions

PDT is a multi-stage process:

Step 1. Preparation of Lesions

Before applying AMELUZ, carefully wipe all lesions with an ethanol or isopropanol-soaked cotton pad to ensure degreasing of the skin.

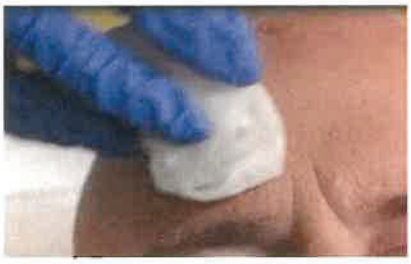


Figure 1A: Degreasing the skin

Thereafter, remove any scaling and crusts and gently roughen all lesion surfaces, taking care to avoid bleeding.

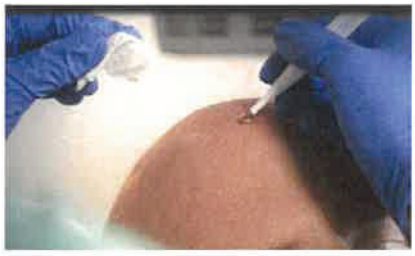


Figure 1B: Removal of scales and crust

Step 2. Application of AMELUZ

Use glove protected fingertips or a spatula to apply AMELUZ. Apply gel approximately 1 mm thick and include approximately 5 mm of the surrounding skin. Use sufficient amount of gel to cover the single lesions or if multiple lesions, the entire area. Application area should not exceed 20 cm^2 and no more than 2 grams of AMELUZ (one tube) should be used at one time. The gel can be applied to healthy skin around the lesions. Avoid application near mucous membranes such as the eyes, nostrils, mouth, and ears (keep a distance of 1 cm from these areas). In case of accidental contact with these areas, thoroughly rinse with water. Allow the gel to dry for approximately 10 minutes before applying occlusive dressing.

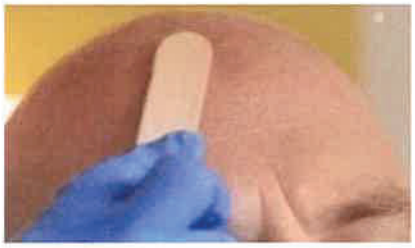


Figure 2: Drug application

Step 3. Occlusion for 3 Hours

Cover the area where the gel has been applied with a light-blocking, occlusive dressing. Following 3 hours of occlusion, remove the dressing and wipe off any remaining gel.

Figure 3: Occlusion

Step 4. Illumination with Red Light

During illumination, patient and medical personnel need to wear suitable protective eyewear.

Immediately after removing occlusion and any remaining gel, illuminate the treatment area with BF-RhodoLED®, a red light source with a narrow spectrum around 635 nm that delivers a light dose of approximately 37 J/cm^2 within 10 minutes. Calibration by the operator is not needed; the illumination time is calculated automatically. Position the lamp head 5-8 cm from the skin's surface. When an area of 8 x 18 cm is illuminated, the effective treatment area is 6 x16 cm. Larger areas can be illuminated in several steps.

Healthy untreated skin surrounding the AK lesions does not need protection during illumination.

Figure 4: Illumination

If for any reason, the lesions cannot be illuminated within 3 hours after AMELUZ application, rinse off the gel with saline and water. For 2 days, protect the lesion sites and surrounding skin from sunlight or prolonged or intense light (e.g., tanning beds, sun lamps).

3. DOSAGE FORMS AND STRENGTHS

Each gram of AMELUZ gel, 10% contains 100 mg of aminolevulinic acid hydrochloride (equivalent to 78 mg of aminolevulinic acid).

4. CONTRAINDICATIONS

AMELUZ is contraindicated in patients with:

- Known hypersensitivity to porphyrins.
- Known hypersensitivity to any of the components of AMELUZ, which includes soybean phosphatidylcholine.
- Porphyria. AMELUZ use may cause uncontrolled phototoxic effects *[see Warnings and Precautions (5.2)]*.
- Photodermatoses. PDT may worsen the phototoxic or photoallergic reactions *[see Warnings and Precautions (5.2)]*.

5. WARNINGS AND PRECAUTIONS

5.1 Risk of BF-RhodoLED Lamp Induced Eye Injury

BF-RhodoLED lamp may cause eye irritation, glare, or injury. Before operating the lamp, personnel must refer to the user manual for specific warnings, cautions, and instructions. Eye exposure to the BF-RhodoLED light must be prevented. Protective eye equipment must be used by patient, healthcare providers and any person present during the illumination period. Avoid staring directly into the light source *[see Dosage and Administration (2)]*.

5.2 Increased Photosensitivity

AMELUZ increases photosensitivity. Avoid sunlight, prolonged or intense light (e.g., tanning beds, sun lamps) on lesions and surrounding skin treated with AMELUZ for approximately 48 hours following treatment whether exposed to illumination or not. Concomitant use of AMELUZ

with other known photosensitizing agents may increase the risk of phototoxic reaction to PDT *[see Drug Interactions (7)]*.

5.3 Risk of Bleeding in Patients with Coagulation Disorders

AMELUZ has not been tested on patients with inherited or acquired coagulation disorders. Special care should be taken to avoid bleeding during lesion preparation in such patients *[see Dosage and Administration (2)]*. Any bleeding must be stopped before application of the gel.

5.4 Ophthalmic Adverse Reactions

Eyelid edema has occurred with AMELUZ application. AMELUZ can cause ophthalmic adverse reactions. AMELUZ is intended for topical use only. Do not apply AMELUZ into the eyes. Rinse eyes with water in case of accidental contact.

5.5 Risk of Mucous Membrane Irritation

AMELUZ can cause mucous membrane irritation. AMELUZ is intended for topical use only. Do not apply AMELUZ to the mucous membranes. Rinse with water in case of accidental contact.

6. ADVERSE REACTIONS

The following adverse reactions are discussed in greater detail in other sections of the labeling:

- Risk of BF-RhodoLED Lamp Induced Eye Injury*[see Warnings and Precautions (5.1)]*.
- Increased Photosensitivity *[see Warnings and Precautions (5.2)]*.
- Risk of Bleeding in Patients with Coagulation Disorders *[see Warnings and Precautions (5.3)]*.
- Ophthalmic Adverse Reactions *[see Warnings and Precautions (5.4)]*.
- Risk of Mucous Membranes Irritation *[see Warnings and Precautions (5.5)]*.

6.1 Clinical Trial Experience

Because clinical trials are conducted under widely varying conditions, adverse reaction rates observed in the clinical trials of a drug cannot be directly compared to rates in the clinical trials of another drug and may not reflect the rates observed in practice.

The clinical program for AMELUZ included three double-blind and placebo-controlled trials (Trials 1, 2, and 3), enrolling a total of 299 subjects that were treated with narrow band light. Trial subjects were adults greater than or equal to 49 years of age, and the majority had Fitzpatrick skin type I, II, or III. No subjects had Fitzpatrick skin type V or VI. Approximately 86% of subjects were male, and all subjects were Caucasian.

For all trials, the enrolled subjects had mild to moderate AKs (Olsen grade 1 and 2) with 4 to 8 lesions on the face and scalp. Overall, 87 placebo-treated subjects (n=16, n=32, n=39) and 212 AMELUZ-treated subjects (n=32, n=55, and n=125) were illuminated with BF-RhodoLED or similar narrow spectrum lamps.

Local skin reactions at the application site were observed in about 99.5% of subjects treated with AMELUZ and narrow spectrum lamps. The most frequent adverse reactions during and after PDT were application site erythema, pain, burning, irritation, edema, pruritus, exfoliation, scab, induration, and vesicles.

Most adverse reactions occurred during illumination or shortly afterwards, were generally of mild or moderate intensity, and lasted for 1 to 4 days in most cases; in some cases, however, they persisted for 1 to 2 weeks or even longer. Severe pain/burning occurred in up to 30% of subjects. In one case, the adverse reactions required interruption or discontinuation of the illumination.

The incidence of common (≥1%, <10%) and very common (≥10%) adverse reactions in randomized, multicenter trials trials at the application site are presented in Table 1.

Table 1: Incidence of Adverse Reactions Occurring at ≥ 1% of the AMELUZ Group and More Frequently than the Vehicle Group in the Actinic Keratosis Trials at the Application Site

Adverse reaction	Vehicle n=87	AMELUZ n=212
Adverse reactions at the application site		
Erythema	34 (39%)	195 (92%)
Pain/Burning	26 (30%)	195 (92%)
Irritation	17 (20%)	153 (72%)
Edema	3 (3%)	75 (35%)
Pruritus	14 (16%)	72 (34%)
Exfoliation	4 (5%)	41 (19%)
Scab	2 (2%)	41 (19%)
Induration	0 (0%)	26 (12%)
Vesicles	1 (1%)	25 (12%)
Paresthesia	2 (2%)	18 (9%)
Hyperalgesia	0 (0%)	10 (5%)
Reaction	2 (2%)	8 (4%)
Discomfort	0 (0%)	7 (3%)
Erosion	0 (0%)	6 (3%)
Discharge	0 (0%)	4 (2%)
Bleeding	0 (0%)	3 (1%)
Pustules	0 (0%)	3 (1%)

Common (≥1%, < 10%) adverse reactions not limited to the application site were chills, headache, and skin exfoliation.

Uncommon (≥ 0.1%, <1%) adverse reactions at the application site for AMELUZ were hemorrhage and swelling. The adverse reactions not limited to the application site were eyelid edema, feeling hot, pain, pyrexia, ulcer, hyperalgesia, rash pustular, nervousness, blister, petechiae, pruritus, scab and skin erosion.

In a clinical trial designed to investigate the sensitization potential of aminolevulinic acid with 216 healthy subjects, 13 subjects (6%) developed allergic contact dermatitis after continuous exposure for 21 days with doses of aminolevulinic acid that were higher than doses normally used in the treatment of AK.

6.2 Postmarketing Experience

In addition to adverse reactions reported from clinical trials, the following adverse reactions have been reported during post-approval use of AMELUZ outside the United States. Because these reactions are reported voluntarily from a population of uncertain size, it is not always possible to reliably estimate their frequency or establish a causal relationship to drug exposure.

Skin and subcutaneous tissue disorders: erythema, swelling, application site inflammation and skin discoloration.
Eye disorders: eye irritation, diplopia, ocular hyperemia, photophobia, and blurred vision.

7. DRUG INTERACTIONS

There have been no formal studies of the interaction of AMELUZ with other drugs. It is possible that concomitant use of other known photosensitizing agents such as St. John's wort, griseofulvin, thiazide diuretics, sulfonylureas, phenothiazines, sulphonamides, quinolones and tetracyclines may enhance the phototoxic reaction to PDT *[see Warnings and Precautions (5.1)]*.

8. USE IN SPECIFIC POPULATIONS

8.1 Pregnancy

Risk Summary

There are no available data on AMELUZ use in pregnant women to inform a drug associated risk. Animal reproduction studies were not conducted with aminolevulinic acid. Systemic absorption of aminolevulinic acid in humans is negligible following topical administration of AMELUZ under maximal clinical use conditions *[see Clinical Pharmacology (12.3)]*. It is not expected that maternal use of AMELUZ will result in fetal exposure to the drug.
The estimated background risk of major birth defects and miscarriage for the indicated population are unknown. In the U.S. general population, the estimated background risk of major birth defects and miscarriage in clinically recognized pregnancies is 2% to 4% and 15% to 20%, respectively.

8.2 Lactation

Risk Summary

No data are available regarding the presence of aminolevulinic acid in human milk, the effects of aminolevulinic acid on the breastfed infant or on milk production. However, breastfeeding is not expected to result in exposure of the child to the drug due to the negligible systemic absorption of aminolevulinic acid in humans following topical administration of AMELUZ under maximal clinical use conditions *[see Clinical Pharmacology (12.3)]*. The developmental and health benefits of breastfeeding should be considered along with the mother's clinical need for AMELUZ and any potential adverse effects on the breastfeeding child from AMELUZ or from the underlying maternal condition.

8.4 Pediatric Use

Safety and effectiveness in pediatric patients below the age of 18 have not been established. AK is not a condition generally seen in the pediatric population.

8.5 Geriatric Use

Of the 384 subjects exposed to AMELUZ in randomized, multicenter clinical trials, 83% (318/384) of the subjects were 65 years old and over. No overall differences in safety or effectiveness were observed between these subjects and younger subjects, but greater sensitivity of some older individuals cannot be ruled out.

10. OVERDOSAGE

10.1 AMELUZ Overdose

AMELUZ overdosage following topical administration has not been reported. If AMELUZ is accidentally ingested, monitoring and supportive care is recommended. The patient should be advised to avoid incidental sunlight exposure for 48 hours after ingestion.

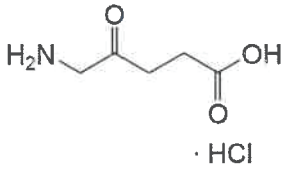
10.2 Red Light Overdose following AMELUZ Administration

There is no information on overdose of red light from the BF-RhodoLED following AMELUZ application.

11. DESCRIPTION

AMELUZ (aminolevulinic acid hydrochloride) gel, 10% for topical use is a non-sterile white-to-yellowish gel. The gel formulation contains a nanoemulsion.

Aminolevulinic acid, a porphyrin precursor, is a white to off-white crystalline solid. It is readily soluble in water, methanol, and dimethylformamide. Its chemical name is 5-amino-4-oxo-pentanoic acid hydrochloride, molecular weight is 167.59 and molecular formula is $C_5H_9NO_3 \cdot HCl$. The structural formula of aminolevulinic acid hydrochloride is represented below:



Each gram of AMELUZ contains 100 mg of aminolevulinic acid hydrochloride (equivalent to 78 mg aminolevulinic acid) as the active ingredient and the following inactive ingredients: xanthan gum, soybean phosphatidylcholine, polysorbate 80, medium-chain triglycerides, isopropyl alcohol, dibasic sodium phosphate, monobasic sodium phosphate, propylene glycol, sodium benzoate and purified water.

12. CLINICAL PHARMACOLOGY

12.1 Mechanism of Action

Photoactivation following topical application of AMELUZ occurs when aminolevulinic acid (prodrug) is metabolized to protoporphyrin IX (PpIX), a photoactive compound which accumulates in the skin. When exposed to red light of a suitable wavelength and energy, PpIX is activated resulting in an excited state of porphyrin molecules. In the presence of oxygen, reactive oxygen species are formed which causes damage to cellular components, and eventually destroys the cells. AMELUZ photodynamic therapy of AK lesions utilizes photoactivation of topically applied AMELUZ resulting from BF-RhodoLED illumination, which provides a red light of narrow spectrum and a light dose of approximately 37 J/cm^2.

12.3 Pharmacokinetics

Pharmacokinetics (PK) of aminolevulinic acid and PpIX was evaluated in a trial of 12 adult subjects with mild to moderate AK with at least 10 AK lesions on the face or forehead. A single dose of one entire tube of AMELUZ (2 grams) was applied under occlusion for 3 hours followed by PDT to a total area of 20 cm^2. The mean ± SD baseline plasma aminolevulinic acid and PpIX concentrations were 20.16 ± 16.53 ng/mL and 3.27 ± 2.40 ng/mL, respectively. In most subjects, an up to 2.5-fold increase of aminolevulinic acid plasma concentrations was observed during the first 3 hours after AMELUZ application. The mean ± SD area under the concentration time curve (AUC_{0-t}) and maximum concentration (C_{max}) for baseline corrected aminolevulinic acid (n=12) were 142.83 ± 75.50 ng.h/mL and 27.19 ± 20.02 ng/mL, respectively. The median Tmax (time at which C_{max} occurred) was 3 hours.

The majority (about 55%) of the PpIX concentrations were below the limit of quantification (LOQ = 1 ng/mL) and baseline corrected values were negative in all subjects except for one. The baseline corrected AUC_{0-t} and C_{max} in the single subject was 0.07 ng.h/mL and 0.29 ng/mL, respectively. PK of aminolevulinic acid and PpIX following treatment on the scalp was not evaluated.

13. NONCLINICAL TOXICOLOGY

13.1 Carcinogenesis, Mutagenesis, Impairment of Fertility

Long-term studies to evaluate the carcinogenic potential of AMELUZ or aminolevulinic acid have not been performed.

Aminolevulinic acid revealed no evidence of mutagenic or clastogenic potential based on the results of three in vitro genotoxicity tests (Ames assay, HPRT test in V79 cells, and Human lymphocyte chromosomal aberration assay) and one in vivo genotoxicity test (mouse micronucleus assay). These genotoxicity studies were conducted without exposure to light. There is a literature report that indicates that aminolevulinic acid may cause genotoxic effects in the presence and in the absence of activating light. These genotoxic effects are likely caused by the formation of reactive oxygen species.

Animal fertility studies have not been conducted with aminolevulinic acid because of the negligible systemic absorption of aminolevulinic acid in humans following topical administration of AMELUZ under maximal clinical use conditions.

14. CLINICAL STUDIES

The efficacy and safety of AMELUZ in combination with PDT using a narrow spectrum (red light lamp) source were evaluated in three randomized, multicenter trials (Trials 1, 2, and 3). Trials 2 and 3 were vehicle-controlled and double-blind. Trial 1 was double-blind with respect to vehicle and observer-blind regarding the active comparator arm. All clinical trials included a follow-up assessment after 6 and 12 months.

In these trials, 212 subjects with 4 to 8 mild to moderate AK lesions on the face/forehead and/or bald scalp were treated with AMELUZ and a narrow band spectrum lamp. Subjects ranged from 49 to 87 years of age (mean 71 years), and 92% had Fitzpatrick skin type I, II, or III. No subjects had Fitzpatrick skin type V or VI. Approximately 86% of subjects were male, and all subjects were Caucasian.

All sessions were comprised of lesion preparation to roughen the surface and remove crusts, application of AMELUZ with occlusion for 3 hours, and removal of the residual gel. Subsequently, the entire treatment area was illuminated with a narrow spectrum red light source, a lamp of either 630 nm or 633 nm and a light dose of approximately 37 J/cm^2. In Trial 3, illumination was performed with BF-RhodoLED, a red light source with a narrow spectrum around 635 nm and a light dose of approximately 37 J/cm^2.

In all trials, the lesions that were not completely cleared 12 weeks after the initial treatment were treated a second time with an identical regimen. In the trials, 42% (88/212) of subjects needed a second treatment.

The primary endpoint for all trials was complete clearance 12 weeks after the last PDT. The results of Trials 1, 2 and 3 are presented in Table 2.

Table 2: Complete Clearance 12 Weeks After the Last Narrow Spectrum PDT in Subjects with Actinic Keratoses

	Narrow Spectrum PDT	
	AMELUZ	Vehicle
Trial 1	106/125 (85%)	5/39 (13%)
Trial 2	27/32 (84%)	2/16 (13%)
Trial 3	50/55 (91%)	7/32 (22%)

Subjects who achieved complete clearance at 12 weeks after the last PDT entered a 12-month follow-up period. In the three trials, subjects who received AMELUZ with the narrowband PDT and achieved complete clearance 12 weeks after the last PDT had recurrence rates of 14%, 11%, and 25%, respectively (at 6 months) and 40%, 22%, and 37%, respectively (at 12 months). Recurrence was defined as the percentage of subjects with at least one recurrent lesion during the 6-month or 12-month follow-up period in subjects with completely cleared lesions 12 weeks after the last PDT.

In a clinical trial designed to investigate the sensitization potential of aminolevulinic acid hydrochloride with 216 healthy subjects, 13 subjects (6%) developed allergic contact dermatitis after continuous exposure for 21 days with doses of aminolevulinic acid hydrochloride that were higher than doses normally used in the treatment of AK.

16. HOW SUPPLIED/STORAGE AND HANDLING

AMELUZ (aminolevulinic acid hydrochloride) gel, 10% is a white-to-yellowish gel. The drug product is supplied in an aluminum tube with a white, high density polyethylene (HDPE) screw cap. Each tube contains 2 g of gel.

NDC 70621-101-01 2 g tube

Store AMELUZ in a refrigerator, 2°C– 8°C (36°F - 46°F). Excursions permitted to 15°C – 30°C (59°F -86°F).

After opening, AMELUZ can be stored for up to 12 weeks in a refrigerator at 2°C – 8°C (36°F - 46°F) if the tube is tightly closed.

17. PATIENT COUNSELING INFORMATION

17.1 Photosensitivity

Advise patients that for approximately 48 hours following treatment to avoid exposure to sunlight, and prolonged or intense light on the treated lesion sites and surrounding skin.

Advise patients to avoid certain medications that may enhance the phototoxic reaction to PDT *[see Warnings and Precautions (5) and Drug Interactions (7)]*.

17.2 Common Adverse Reactions

Inform patients that treatment with AMELUZ in combination with PDT may result in adverse reactions which include local skin reactions at the application site such as erythema, pain/burning, irritation, edema, pruritus, exfoliation, induration, scab, and vesicles.

AMELUZ and BF-RhodoLED are registered trade marks of Biofrontera Pharma GmbH.

PATENT INFO

US patent 6,559,183 and pending patent application US 2009/0324727

Distributed by:

Biofrontera Inc.

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Wakefield, MA 01880

USA